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10/826,843	04/15/2004	Robert T. Lyons	17684 (AP)	2070
51957	7590	02/21/2008		
ALLERGAN, INC. 2525 DUPONT DRIVE, T2-7H IRVINE, CA 92612-1599			EXAMINER FAY, ZOHREH A	
			ART UNIT 1612	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/826,843  
Filing Date: April 15, 2004  
Appellant(s): LYONS ET AL.

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Brent Johnson  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed November 30, 2007 appealing from the  
Office action mailed May 9, 2007.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

5,576,311	Guy	11-1996
5,472,954	Loftsson	12-1995

WO 02/089815

Lyons

11-2002

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15 and 19, 21, 22, 23 and 26 are rejected under 35 U.S.C. 102 (b) as being anticipated by Guy (U.S. Patent 5,576,311).

Guy teaches the use of the claimed cyclodextrin derivatives such as hydroxyl propyl cyclodextrin in combination with corticoid such as prednisolone acetate in an ophthalmic/pharmaceutical formulation for the treatment of ophthalmic disorders. See column 1, lines 38-65, column 2, line 55, column 3, lines 1-10, column 3, lines 30-37, column 4, and lines 1-15.

Claims 1-19, 21, 22, 23 and 26 are rejected under 35 U.S.C. 102 (b) as being anticipated by the WO 02/089815.

The WO Patent teaches the use of prednisolone acetate in combination with the claimed cyclodextrin and HPMC in an ophthalmic formulation for the delivery to the eye. See page 10, lines 8-13, page 12, lines 11-26 and the table in page 14. The above teachings read on the claimed invention.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guy (U.S. Patent 5,576,311) in view of Loftsson (U.S. Patent 5,472,954).

Guy teaches the use of the claim-designated cyclodextrin such as hydroxy propyl cyclodextrin in combination with corticosteroids, such as prednisolone or prednisolone acetate in a pharmaceutical formulation for the treatment of ophthalmic disorders. See column 1, lines 38-65, column 2, line 55, column 3, lines 1-10, column 3, lines 30-37,

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column 4, lines 1-15. The above reference differs from the claimed invention in the presence of hydroxypropylmethylcellulose. Loftsson et al. teach the use of the claimed designated cyclodextrin in combination with hydroxypropylmethylcellulose and steroids in an ophthalmic formulation. See claims 74, 76, 83 and 94. It would have been obvious to a person skilled in the art to incorporate a hydroxypropylmethyl cellulose into the teaching of the primary reference, considering that the secondary reference teaches the addition of hydroxypropylmethyl cellulose to the claimed cyclodextrin as old and well known.

One skilled in the art would have been motivated to combine the teachings of the above reference, since one relates to the use of hydroxypropyl cyclodextrin in combination with corticosteroids and a polymer in an ophthalmic formulation for the treatment of ophthalmic disorders, and the other relates to the addition of hydroxypropylmethyl cellulose to the claimed cyclodextrin in an ophthalmic formulation as old. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 16-18 are properly rejected under 35 U.S.C. 103.

#### **(10) Response to Argument**

Appellant's arguments regarding the 102 (b) and 103 (a) rejections have been noted, but are not deemed to be persuasive. Applicant alleges criticality to the delivery of the claimed combination to vitreous humor or structures posterior to vitreous humor. The allegation is not well taken. It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (250 USPO 594) discuss support of rejection wherein the prior art discloses

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subject matter, which there is reason to believe inherently includes function that are newly cited or is identical to product instantly claimed. In such situation the burden is shifted to the applicant to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter in fact is inherent in the prior art reference. *Schering Corp v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("The fact that a characteristic is a necessary feature or result of a prior-art embodiment is enough for inherent anticipation, even if the fact was unknown at the time of the prior art invention"). In the instant case appellant is using the same composition as prior art, therefore it is expected that such composition would inherently act the same as the composition of the instant application.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Zohreh A Fay/

Primary Examiner, Art Unit 1612



Art Unit: 1612

Conferees:

A handwritten signature in cursive script, appearing to read "Fredrick Krass", written over a horizontal line.

Fredrick Krass

Supervisory Patent Examiner

Art Unit, 1612

A handwritten signature in cursive script, appearing to read "Sreeni Padmanabhan", written over a horizontal line.

Sreeni Padmanabhan

Supervisory Patent Examiner

Art Unit, 1617